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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/813,319 | 03/21/2001 | Ming-Hui Wei | CL001066-CIP | 1556 |

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| EXAMINER |
|---|
| BERTOGLIO, VALARIE E |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1632 | |

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/813,319 | WEI ET AL. | |
| | Examiner | Art Unit | |
| | Valarie Bertoglio | 1632 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 3, drawn to an antibody that selectively binds to an amino acid sequence shown in SEQ ID N0:2 or an ortholog or fragment thereof , classified in class 530, subclass 387.9.

II. Claim 6, drawn to a gene chip comprising a nucleic acid that encodes an allelic variant of an amino acid sequence show in SEQ ID NO:2 or a fragment thereof, classified in class 435, subclass 285.1.

III. Claim 7, drawn to a transgenic non-human animal comprising a nucleic acid that encodes an allelic variant of an amino acid sequence show in SEQ ID NO:2 or a fragment thereof, classified in class 800, subclass 8.

IV. Claims 8 and 9, drawn to a nucleic acid that encodes the amino acid sequence show in SEQ ID NO:2, an allelic variant of an amino acid sequence show in SEQ ID NO:2 or a fragment thereof and cells comprising said nucleic acid, classified in class 536, subclass 23.1.

V. Claims 10 and 11, drawn to an isolated peptide consisting of an amino acid sequence shown in SEQ ID N0:2 or an ortholog or fragment thereof, a method for producing the peptide, and a method of using the peptide to identify an agent, classified in class 530;530, subclass 300;350.

VI. Claim 13, drawn to a method of detecting the presence of a nucleic acid consisting of an amino acid sequence shown in SEQ ID N0:2 or an allelic variant, an ortholog or fragment thereof, classified in class 435, subclass 6.

VII. Claims 14 and 15, drawn to a method of identifying a modulator of a peptide, classified in class 435, subclass 6.

VIII. Claim 12, drawn to a method of detecting the presence of an isolated peptide consisting of an amino acid sequence shown in SEQ ID N0:2 or an ortholog or fragment thereof, classified in class 435, subclass 7.1.

IX. Claim 16, drawn to a method of identifying an agent that binds a peptide, classified in class 435, subclass7.1.

X. Claims 17 and 18, drawn to a pharmaceutical reagent that binds to an isolated peptide consisting of an amino acid sequence shown in SEQ ID N0:2 or an ortholog or fragment thereof , unclassifiable.

XI. Claim 19, drawn to a method of identifying a modulator of the expression of a peptide consisting of an amino acid sequence shown in SEQ ID N0:2 or an ortholog or fragment thereof, classified in class 435, subclass 7.21.

If elected, further restriction of Invention X will be necessary when the agent is identified.

The inventions are distinct, each from the other because of the following reasons:

Invention I and each of Inventions II-V and X are patentably distinct because, the antibody can be used to detect protein while the gene chip of Invention II can be used in gene expression assays, the transgenic non-human animal of Invention III can be used to screen drugs in vivo, the nucleic acid of Invention III can be used to transform cells in vitro, the peptide of Invention V can be used to identify modulators, and the pharmaceutical of Invention X can be

used to treat disease. The protocols and reagents required for the antibody and each of the products of Inventions II-V and X are materially distinct and separate. The antibody does not require the nucleic acid, the gene chip, the transgenic non-human animal or the pharmaceutical and neither the nucleic acid, the gene chip the transgenic non-human animal nor the pharmaceutical require the antibody. The products of each of Invention II-V and X are classified separately. The burden required to search Invention I together with any of Inventions II-V or X would be undue.

Invention I and each of Inventions VI- IX and XI are patentably distinct because, the antibody of Invention I can be used to screen for binding proteins while the methods of Invention VI can be used to detect the presence of a nucleic acid, the method of Invention VII can be used to identify a modulator of a peptide, the methods of Invention VIII can be used to detect the presence of an isolated peptide, the methods of Invention IX can be used to identify an agent that binds a peptide, and the methods of Invention XI can be used to identify a modulator of gene expression. The protocols and reagents required for the peptide and the methods are materially distinct and separate. The antibody does not require any of the methods and the methods do not require the antibody. The burden required to search Invention I together with any of Inventions VI-IX and XI would be undue.

Invention II and each of Inventions III-V and X are patentably distinct because, the gene chip of Invention II can be used in gene expression assays while the transgenic non-human animal of Invention III can be used to screen drugs in vivo, the nucleic acid of Invention IV can be used to transform cells in vitro, the peptide of Invention V can be used to identify modulators, and the pharmaceutical of Invention X can be used to treat disease. The protocols and reagents

required for the gene chip and each of the products of Inventions III-V and X are materially distinct and separate. The gene chip does not require the transgenic non-human animal, the nucleic acid of Invention IV, the peptide of Invention V, or the pharmaceutical of Invention X and neither the transgenic non-human animal nor the nucleic acid nor the peptide nor the pharmaceutical require the gene chip. The products of each of Inventions II-V and X are classified separately. The burden required to search Invention II together with any of Inventions III-V or X would be undue.

Invention II and each of Inventions VI- IX and XI are patentably distinct because, the gene chip of Invention II can be used in gene expression assays while the methods of Invention VI can be used to detect the presence of a nucleic acid, the method of Invention VII can be used to identify a modulator of a peptide, the methods of Invention VIII can be used to detect the presence of an isolated peptide, the methods of Invention IX can be used to identify an agent that binds a peptide, and the methods of Invention XI can be used to identify a modulator of gene expression. The protocols and reagents required for the peptide and the methods are materially distinct and separate. The gene chip does not require any of the methods and the methods do not require the gene chip. The burden required to search Invention II together with any of Inventions VI-IX and XI would be undue.

Invention III and each of Inventions IV,V and X are patentably distinct because, the transgenic nonhuman animal of Invention III can be used to screen drugs in vivo while the nucleic acid of Invention IV can be used to transform cells in vitro, the peptide of Invention V can be used to identify modulators, and the pharmaceutical of Invention X can be used to treat disease. The protocols and reagents required for the transgenic non-human animal and each of

the products of Inventions IV,V and X are materially distinct and separate. The transgenic non-human animal does not require the nucleic acid of Invention IV, the peptide of Invention V, or the pharmaceutical of Invention X and neither the nucleic acid nor the peptide nor the pharmaceutical require the transgenic non-human animal. The products of each of Inventions III-V and X are classified separately. The burden required to search Invention III together with any of Inventions IV,V or X would be undue.

Invention III and each of Inventions VI- IX and XI are patentably distinct because, the transgenic non-human animal of Invention III can be used to screen drugs in vivo while the methods of Invention VI can be used to detect the presence of a nucleic acid, the method of Invention VII can be used to identify a modulator of a peptide, the methods of Invention VIII can be used to detect the presence of an isolated peptide, the methods of Invention IX can be used to identify an agent that binds a peptide, and the methods of Invention XI can be used to identify a modulator of gene expression. The protocols and reagents required for the transgenic non-human animal and the methods are materially distinct and separate. The transgenic non-human animal does not require any of the methods and the methods do not require the transgenic non-human animal. The burden required to search Invention III together with any of Inventions VI-IX and XI would be undue.

Invention IV and each of Inventions V and X are patentably distinct because, the nucleic acid of Invention IV can be used to transform cells in vitro while the peptide of Invention V can be used to identify modulators, and the pharmaceutical of Invention X can be used to treat disease. The protocols and reagents required for the nucleic acid and each of the products of Inventions V and X are materially distinct and separate. The nucleic acid does not require the

peptide of Invention V or the pharmaceutical of Invention X and neither the peptide nor the pharmaceutical require the nucleic acid. The products of each of Inventions IV,V and X are classified separately. The burden required to search Invention IV together with either of Inventions V or X would be undue.

Invention IV and each of Inventions VI- IX and XI are patentably distinct because, the nucleic acid of Invention IV can be used to transform cells in vitro while the methods of Invention VI can be used to detect the presence of a nucleic acid, the method of Invention VII can be used to identify a modulator of a peptide, the methods of Invention VIII can be used to detect the presence of an isolated peptide, the methods of Invention IX can be used to identify an agent that binds a peptide, and the methods of Invention XI can be used to identify a modulator of gene expression. The protocols and reagents required for the nucleic acid and the methods are materially distinct and separate. The nucleic acid does not require any of the methods and the methods do not require the nucleic acid. The burden required to search Invention IV together with any of Inventions VI-IX and XI would be undue.

Invention V and each of Inventions VI- IX and XI are patentably distinct because, the peptide of Invention V can be used to generate antibodies while the methods of Invention VI can be used to detect the presence of a nucleic acid, the method of Invention VII can be used to identify a modulator of a peptide, the methods of Invention VIII can be used to detect the presence of an isolated peptide, the methods of Invention IX can be used to identify an agent that binds a peptide, and the methods of Invention XI can be used to identify a modulator of gene expression. The protocols and reagents required for the nucleic acid and the methods are materially distinct and separate. The peptide does not require any of the methods and the

methods do not require the peptide. The burden required to search Invention V together with any of Inventions VI-IX and XI would be undue.

Invention V and X are patentably distinct because, the peptide of Invention V can be used to identify modulators, while the pharmaceutical comprising a peptide binding agent can be used to treat disease. The protocols and reagents required for the peptide and the pharmaceutical comprising a peptide-binding agent are materially distinct and separate. The peptide does not require pharmaceutical and the pharmaceutical does not require the peptide. The products of each of Inventions V and X are classified separately. The burden required to search Inventions V and X together would be undue.

Invention VI and each of Inventions VII- IX and XI are patentably distinct because, the methods of Invention VI can be used to detect the presence of a nucleic acid while, the method of Invention VII can be used to identify a modulator of a peptide, the methods of Invention VIII can be used to detect the presence of an isolated peptide, the methods of Invention IX can be used to identify an agent that binds a peptide, and the methods of Invention XI can be used to identify a modulator of gene expression. The methods of each of inventions VI-IX and XI are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. The burden required to search Invention VI together with any of Inventions VII-IX and XI would be undue.

Inventions VI and X are patentably distinct because, methods of Invention VI can be used to detect the presence of a nucleic acid, while the pharmaceutical can be used to treat disease. The protocols and reagents required for the methods and the pharmaceutical are materially

distinct and separate. The methods do not require pharmaceutical and the pharmaceutical does not require the methods. Inventions VI and X are classified separately. The burden required to search Inventions VI and X together would be undue.

Invention VII and each of Inventions VIII- IX and XI are patentably distinct because, the method of Invention VII can be used to identify a modulator of a peptide while the methods of Invention VIII can be used to detect the presence of an isolated peptide, the methods of Invention IX can be used to identify an agent that binds a peptide, and the methods of Invention XI can be used to identify a modulator of gene expression. The methods of each of inventions VII-IX and XI are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. The burden required to search Invention VII together with any of Inventions VIII-IX and XI would be undue.

Inventions VII and X are patentably distinct because the methods of Invention VII can be used to identify a modulator of a peptide, while the pharmaceutical comprising a peptide binding agent can be used to treat disease. The protocols and reagents required for the methods and the pharmaceutical are materially distinct and separate. The methods do not require pharmaceutical and the pharmaceutical does not require the methods. Inventions VII and X are classified separately. The burden required to search Inventions VII and X together would be undue.

Invention VIII and each of Inventions IX and XI are patentably distinct because, the method of Invention VIII can be used to detect the presence of an isolated peptide while the methods of Invention IX can be used to identify an agent that binds a peptide, and the methods of Invention XI can be used to identify a modulator of gene expression. The methods of each of

inventions IX and XI are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. The burden required to search Invention VIII together with either of Inventions IX and XI would be undue.

Inventions VIII and X are patentably distinct because the methods of Invention VIII can be used to detect the presence of an isolated peptide, while the pharmaceutical comprising a peptide binding agent can be used to treat disease. The protocols and reagents required for the methods and the pharmaceutical are materially distinct and separate. The methods do not require pharmaceutical and the pharmaceutical does not require the methods. Inventions VIII and X are classified separately. The burden required to search Inventions VIII and X together would be undue.

Inventions IX and X are patentably distinct because the methods of Invention IX can be used to identify an agent that binds to a peptide, while the pharmaceutical can be used to treat disease. The protocols and reagents required for the methods and the pharmaceutical are materially distinct and separate. The methods do not require pharmaceutical and the pharmaceutical does not require the methods. Inventions IX and X are classified separately. The burden required to search Inventions VII and X together would be undue.

Inventions IX and XI are patentably distinct because, the method of Invention IX can be used to identify an agent that binds a peptide while the method of Invention XI can be used to identify a modulator of gene expression. The methods of each of Inventions IX and XI are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct

protocols and reagents. The burden required to search Invention IX and XI together would be undue.

Claims 1,2,20 and 21 link(s) inventions V, VII-IX and XI . The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1,2,20, and 21. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 4,5,22 and 23 link(s) inventions II-IV and VI . The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1,2,20, and 21. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional

application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on Mon-Weds 6:00-2:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

PETER PARAS
PATENT EXAMINER

Valarie Bertoglio
Examiner
Art Unit 1632